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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,298	08/08/2001	Vincent Bryan	46739/262600	3319
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HAYNES AND BOONE, LLP			EXAMINER	
901 Main Street			PHILOGENE, PEDRO	
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Dallas, TX 75202			ART UNIT	PAPER NUMBER
			3733	
			MAIL DATE	DELIVERY MODE
			10/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/924,298

Applicant(s)

BRYAN ET AL.

Examiner

Pedro Philogene

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 93-96, 101-103, 106-110, 112, 113, 121 and 122 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 114-119 is/are allowed.
- 6) ☒ Claim(s) 91 and 92 is/are rejected.
- 7) ☒ Claim(s) 1-17, 20, 22-44, 56-61, 66-71, 74-76, 84-90, 120 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 1-17,20-44,56-61,66,67,70,71,74-76,81,82,84-97,101-103,106-110 and 112-122.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 56-61 are rejected under 35 U.S.C. 102(b) as being anticipated by
Buttner-Janz et al. (5,401,269)

With respect to the above claims Buttner-Janz et al disclose a central body (3) and articulable between two shells (1,2), the central body being slidable relative to at least one of the two shells, wherein the central body has an upper and lower contact surfaces; as best seen in FIGS.1-11, and wherein in the absence of a compressive load, an upper shoulder is recessed into a portion of the perimeter (7) of the upper contact surface and a lower shoulder is recessed into a portion of the perimeter (7) of the lower contact surface; as best seen in FIGS.1-15; Wherein an upper shoulder extends around a portion of the perimeter of the upper contact surface and a lower shoulder extends around a portion of the perimeter of the lower contact surface and further wherein the upper shoulder defines a ledge, as best seen in FIGS.1-4,8,9, 15, indented into the perimeter of the of the upper contact surface of the central body; as set forth in column 2, line 63-68, column 3, lines 1-167, column 4, lines 1-37, and as best seen in FIGS.1-11.

Claims 81,82, 84,85, 120 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryan et al. (5,674,296).

With respect to the above claims, Bryan et al disclose a bone joint implant comprising a central body (2) positioned between two opposing shells (3,4) and slidable relative to at least one of the two shells, wherein at least one shell has a first edge that includes a radial stop (the bottom part of the groove 402) extending generally axially from the a portion thereof, wherein the first edge has an outer circumference groove (402) therein and wherein the radial stop is adapted to (capable of) contact a shoulder formed in the central body when translational, flexural, or extensional forces are applied to the implant, as best seen FIG. 13,14, and at least one shell has an edge that includes a tab (30) (the upper part of the groove (402) extending generally axially from a portion thereof, the radial stop and the tab are on the same shell and they extend from the shell opposite directions and wherein the radial stop is adapted to (capable of) contact a shoulder formed in the central body when translational, flexural, or extensional forces are applied to the implant; as best seen in FIGS.13,14.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,4-9,20,13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buttner-Janz et al. (5,401,269) in view of Buechel et al. (5,868,796).

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With respect to the above claims Buttner-Janz et al disclose a central body (3) and articable between two shells (1,2), the central body having a resilient, deformable portion and a coating material encasing the central body wherein the resilient deformable portion allows motion in the joint implant and the coating material has a different hardness from the resilient, deformable portion; a motion limiting device; as best seen in FIGS.8-15; a post (13) in the shells in the inner surface of the shells; as set forth in column 2, line 63-68, column 3, lines 1-167, column 4, lines 1-37, and as best seen in FIGS.1-11.

It is noted that Buttner-Janz et al did not teach of a an upper portion and lower portion of the outer surface of the central body are harder than an interior region of the centralbody disposed between the upper and lower portions; as claimed by applicant. However, in a similar art, Buechel et al evidences the use of a core having an outer body that is harder than the interior of the core for preventing leaching of ions from the substrate into adjacent body tissue and for preventing wear.

Therefore, given the teaching of Buechel et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Buttner-Janz et al. as taught by Buechel et al, for preventing leaching of ions from the substrate into adjacent body tissue and for preventing wear.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 10-12,22,24-37,120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buttner-Janz et al. (5,401,269) in view of Buechel et al. (5,868,796) in view of Bryan et al. (5,674,296).

With respect to the above claims, it is noted that Buttner-Janz/Buechel et al disclose all the limitations, except for a flexible sheath defining an enclosed cavity and a circumferential groove adapted to receive a retaining ring and tab extending in the shells; as claimed by applicant. However, in a similar art, Bryan et al evidences the use of an implant having a flexible sheath a circumferential groove, a ring, a tab and a concaval-convex shells to provide a watertight seal to prevent the migration of fluids between the implant and adjacent parts of the anatomy.

Therefore, given the teaching Bryan et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Butter-Janz et al., as taught by Bryan et al., to provide a watertight seal to prevent the migration of fluids between the implant and adjacent parts of the anatomy.

Claims 74-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuhrmann et al. (5,002,576) in view of Ray et al. (6,132,465).

With respect to the above claims, Fuhrmann et al disclose a bone joint implant comprising a sleeve (1) positioned between two opposing shells (3,4) has an upper and

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lower contact surface, and at least one sealable opening (21) in at least one of the shells, for the introduction of the lubricant into the implant after the implant has been assembled; as set forth in column 2, lines 50-68, column 3, lines 1-68, column 4, lines 1-12; and as best seen in FIGS. 1-4.

It is noted that Furhmann et al did not teach of the introduction of a lubricant material between the central body and the opposing shells; as claimed by applicant. However, in a similar art, Ray et al evidence the use of implant having a core and the introduction of lubricant to create an increase volume in the nucleus cavity revitalizing the overall disc space.

Therefore, given the teaching of Ray et al it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Furhmann et al; as taught by Ray et al., to create an increase volume in the nucleus cavity revitalizing the overall disc space.

Claim 3, is rejected under 35 U.S.C. 103(a) as being unpatentable over Buttner-Janz et al. (5,401,269) in view Buechel et al. (5,868,796) in view of Fuhrmann et al. (5,002,576).

It is noted that the above combination of references did not teach of a liquid lubricant, which occupies at least a portion of the cavity and a closable passage between its outer surface and its inner surface; as claimed by applicant. However, in a similar art, Fuhrmann et al., evidence the use of openings in the shells to serve to fill or ventilate the interior of the implant.

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Therefore, given the teaching of Fuhrmann et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Buttner-Janz/Buechel/Bryan et al, as taught by Fuhrmann et al., to serve to fill or ventilate the interior of the implant.

Claims 16,17, 23,28-44, 66,67,70,71, 86-89,90, are rejected under 35 U.S.C. 103(a) as being unpatentable over Buttner-Janz et al. (5,401,269) in view Buechel et al. (5,868,796) in view of Bryan et al. (5,764,296) in view of Fuhrmann et al. (5,002,576).

With respect to the above claims, it is noted that the above combination of references teaches all the limitations; except for openings in the shell for injecting a liquid lubricant into the cavity; as claimed by applicant. However, in a similar art, Fuhrmann et al., evidence the use of openings in the shells to serve to fill or ventilate the interior of the implant.

Therefore, given the teaching of Fuhrmann et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Buttner-Janz/Buechel/Bryan et al, as taught by Fuhrmann et al., to serve to fill or ventilate the interior of the implant.

As to the language "adapted to being sealed with a plug" it is obvious that the opening of Fuhrmann et al is adapted to being sealed by a plug.

Allowable Subject Matter

Claims 91,92 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 114-119 are allowed.

Response to Amendment

Applicant's arguments filed 8/8/07 have been fully considered but they are not persuasive. Applicant stated that the combination fails to disclose "a deformable, resilient central body disposed between the inner surfaces of the shells comprising an outer surface wherein an upper portion and a lower portion of the outer surface of the central body are harder than an interior region of the central body disposed between the upper and lower portion". Applicant's attention is directed to Buechel et al (5,868,796) where a prosthesis with biologically inert wear resistant surface is disclosed. As to an upper shoulder recessed into apportion of the perimeter of the upper contact surface; Buttner-Janz et al disclose a shoulder (FIGS.8, 9, 12-15) recessed into a portion of the perimeter of the upper contact surface; as claimed by applicant. Applicant further stated: the Fuhrmann patent at least fails to disclose an implant including "at least two opposing shells, a central body disposed between the two opposing shells and at least one sealable opening for the introduction of a lubricant into the implant between the central body and the opposing shells..." The reference to Fuhrmann is now being combined with the patent of Ray et al where an implant having a core (22), shells (30,32) , and an opening (36) for lubrication. As to the limitations: "wherein at least both shells include openings", it would have been obvious to one having ordinary skill in the

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art at the time the invention was made to duplicate the opening in the first and second shells, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. As to the recitation "wherein the closable passage is configured in a manner that permits the introduction of a lubricant into the implant between the central body and the opposing shells", with regard to the recitation that an element is "configured to" or "configured for", it has been held that the recitation that an element is "configured to" or "configured for" perform(ing) a function is not a positive limitation but requires the ability to so perform. It does not limitation in any patentable sense. In addition the manner in which a device is intended to be employed, does not differentiate the claimed apparatus from the prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ2d 1647 (1887)

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivational statements in each of the rejections under 103 (a) were taken from the references themselves in most cases from the modifying secondary references. It is therefore the belief of the Examiner that there, in fact, is motivation for making each of the

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combinations set forth above. Furthermore, the question is not whether the combination was obvious to the applicant but whether the combination was obvious to a person with ordinary skill in the art. Given the problem to be solved, under the correct analysis, any need or problem known in the field and addressed by the patents can provide a reason for combining the elements in the manner claimed. It is common sense that familiar items may have obvious uses beyond their primary purposes, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like a piece of a puzzle. In addition, where there is a design need or market pressure to solve a problem and there are a finite or identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp.

Finally, in *Sakraida v. AG Pro, Inc.*, 425 US 237 (1976) the court derived from the precedents the conclusion that when a patent "simply arranges old elements with each performing the same function it had been known to perform" and yields no more than one would expect from such arrangement, the combination is obvious.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

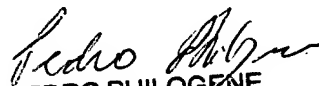
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pedro Philogene
October 16, 2007


PEDRO PHILOGENE
PRIMARY EXAMINER